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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

COOK, REBECCA

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/827,428	ORLOW ET AL.
	<b>Examiner</b> Rebecca Cook	<b>Art Unit</b> 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 27 November 2002.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-92 is/are pending in the application.

4a) Of the above claim(s) 1-69, 74, 76-81 and 83-90 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 70-73, 75, 82, 91 and 92 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

Applicants have elected species (d) for examination. Claim 75 will be examined to the extent that it reads on the elected species.

Claims 91 and 92 will be examined to the extent that they read on the elected invention and species.

Claims 70-73, 91-92 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the elected species of claim 73, does not reasonably provide enablement for any and all intended compounds of the composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. It would take undue experimentation to determine which compounds would yield a composition for reducing skin pigmentation. Medline 6714260 and MEDLINE 89379530 disclose that chlorpromazine, a phenothiazine compound intended for use in the instant invention, produces skin pigmentation.

Claims 70-73, 75, 91-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is confusing as to whether the compound of the instant composition and kit reduces skin pigmentation by effecting and altering late endosomal/lysosomal trafficking in a skin cell (claims 70-73, 75, 82) or modulates melanogenesis by inhibiting late endosomal/lysosomal trafficking (claims 91-92). Additionally, it is not clear in claim 70 whether "alteration" is intended to mean inhibit or activate late endosomal/lysosomal

trafficking. Furthermore, it is not clear if in claims 91 and 92 "modulate" is intended to mean increase or decrease skin pigmentation.

In claim 71 the recitation "contacting the melanocyte" renders it unclear if the intended use of the composition is in vivo or in vivo.

There is no antecedent basis in claim 73 for compound II of claim 82.

In claim 82 compound III is confusing because CH3 on position 15 gives the carbon a valence of 5.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 70-72 are rejected under 35 U.S.C. 102(b) as being anticipated by CA126:190762 (abstract, lines 1-5). The reference discloses melanin formation inhibitors that are used to reduce skin pigmentation. The claims appear to differ over the reference in reciting a compound that affects an alteration in late endosomal/lysosomal trafficking in a skin cell and has certain properties. However, it would be inherent that a compound that reduces skin pigmentation would have these properties.

Claims 70-73, 75, 82 are rejected under 35 U.S.C. 102(a or b) as being anticipated by CA130:295103 (abstract, lines 24-26) or EMBASE 1998386460 (abstract, lines 15-17).

The references disclose compounds that effect an alteration in late endosomal/lysosomal trafficking. The claims appear to differ over the references in reciting a composition for reducing skin pigmentation comprising a compound that effects an alteration in late endosomal/lysosomal trafficking. However, it would be inherent that a compound that has the property of effecting an alteration in late endosomal/lysosomal trafficking would also be able to reduce skin pigmentation.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 91-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over CA126:190762 (abstract, lines 1-5), CA130:295103 (abstract, lines 24-26) or EMBASE 1998386460 (abstract, lines 15-17).

The references each teach a compound that is used to reduce skin pigmentation or effect an alteration in late endosomal/lysosomal trafficking, as recited above. The instant claims recite a kit comprising a compound which also may contain a set of written instruction. However, no unobviousness is seen in a kit comprising a known compound. Furthermore, applicants' nominal recitation of instructions for use being

provided with the kit fails to aid in imparting any patentable weight since the printed matter would not present any unusual and/or unexpected requirement apart from conventional and well known procedures. It is well settled that instructions cannot be relied upon to distinguish over well known pharmaceutical formulations, in the absence of some distinguishing procedure or step.

Applicants are requested to identify any related cases in which there may be double patenting.

Applicants are requested to submit an IDS.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



REBECCA COOK  
PRIMARY EXAMINER  
GROUP 1200, 614

January 23, 2003